

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: Julian Edward Sale et al.

Serial Number: 10/733,532

Filing Date: December 11, 2003

Title: Method for generating diversity

Group Art Unit: 1636

Examiner: Daniel M. Sullivan

CONFIRMATION NO: 9057

Certificate of Electronic Filing

I hereby certify that the attached Information Disclosure Statement and all marked attachments are being deposited by Electronic Filing on August 3, 2007 by using the EFS – Web patent filing system and addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

By: Ann Lygas
Ann Lygas

Date: August 3, 2007

Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.97

Sir:

Applicant hereby submits an Information Disclosure Statement along with attached form(s) PTO/SB/08. A copy of each listed publication is submitted, if required, pursuant to 37 CFR §§1.97-1.98, as indicated below.

Applicant respectfully requests that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicant further requests that the Examiner initial and return the attached forms PTO/SB/08 in accordance with MPEP §609.

Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in §1.56.

- A. ☐ 37 CFR §1.97(b). This Information Disclosure Statement should be considered by the Office because:
- ☐ (1) It is being filed within 3 months of the filing date of a national application and is other than a continued prosecution application under §1.53(d);
-- OR --
 - ☐ (2) It is being filed within 3 months of entry of the national stage as set forth in §1.491 in an international application;
-- OR --
 - ☐ (3) It is being filed before the mailing of a first Office action on the merits;
-- OR --
 - ☐ (4) It is being filed before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
- B. ☒ 37 CFR §1.97(c). Although this Information Disclosure Statement is being filed after the period specified in 37 CFR §1.97(b), above, it is filed before the mailing date of the earlier of (1) a final office action under §1.113, (2) a notice of allowance under §1.311, or (3) an action that otherwise closes prosecution on the merits, this Information Disclosure Statement should be considered because it is accompanied by one of:
- ☐ a statement as specified in §1.97(e) provided concurrently herewith;
-- OR --
 - ☒ a fee of \$180.00 as set forth in §1.17(p) authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- C. ☐ 37 CFR §1.97(d). Although this Information Disclosure Statement is being filed after the mailing date of the earlier of (1) a final office action under §1.113 or (2) a notice of allowance under §1.311, it is being filed before payment of the issue fee and should be considered because it is accompanied by:
- i. a statement as specified in §1.97(e);
-- AND --
 - ii. a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this Statement.
- D. ☐ 37 CFR §1.97(e). Statement.
- ☐ A statement is provided herewith to satisfy the requirement under 37 CFR §§1.97(c);
-- AND/OR --
 - ☐ A statement is provided herewith to satisfy the requirement under 37 CFR §§1.97(d);
-- AND/OR --
 - ☐ A copy of a dated communication from a foreign patent office clearly showing that the information disclosure statement is being submitted within 3 months of the filing date on the communication is provided in lieu of a statement under 37 C.F.R. § 1.97(e)(1) as provided for under MPEP 609.04(b) V.
- E. ☐ Statement Under 37 C.F.R. §1.704(d). Each item of information contained in the information disclosure statement was first cited in a communication from a foreign patent office in a counterpart application that was received by an individual designated in § 1.56(c) not more than thirty (30) days prior to the filing of this information disclosure statement. This statement is made pursuant to the

requirements of 37 C.F.R. §1.704(d) to avoid reduction of the period of adjustment of the patent term for Applicant(s) delay.

F. ☒ 37 CFR §1.98(a)(2). The content of the Information Disclosure Statement is as follows:

☐ Copies of each of the references listed on the attached Form PTO/SB/08 are enclosed herewith.

-- OR --

☒ Copies of U.S. Patent Documents (issued patents and patent publications) listed on the attached Form PTO/SB/08 are NOT enclosed.

-- AND/OR --

☒ Copies of Foreign Patent Documents and/or Non Patent Literature Documents listed on the attached Form PTO/SB/08 are enclosed in accordance with 37 CFR §1.98 (a)(2).

-- AND/OR --

☐ Copies of pending unpublished U.S. patent applications are enclosed in accordance with 37 CFR §1.98(a)(2)(iii).

G. ☐ 37 CFR §1.98(a)(3). The Information Disclosure Statement includes non-English patents and/or references.

☐ Pursuant to 37 CFR §1.98(a)(3)(i), a concise explanation of the relevance of each patent, publication or other information provided that is not in English is provided herewith.

☐ Pursuant to MPEP 609(B), an English language copy of a foreign search report is submitted herewith to satisfy the requirement for a concise explanation where non-English language information is cited in the search report.

-- OR --

☐ A concise explanation of the relevance of each patent, publication or other information provided that is not in English is as follows: _____

☐ Pursuant to 37 CFR §1.98(a)(3)(ii), a copy of a translation, or a portion thereof, of the non-English language reference(s) is provided herewith.

H. ☐ 37 CFR §1.98(d). Copies of patents, publications and pending U.S. patent applications, or other information specified in 37 C.F.R. § 1.98(a) are not provided herewith because:

☐ Pursuant to 37 CFR §1.98(d)(1) the information was previously submitted in an Information Disclosure Statement for another application under which this application claims priority for an earlier effective filing date under 35 U.S.C. 120.

Application in which the information was submitted: _____

Information Disclosure Statement(s) filed on: _____

AND

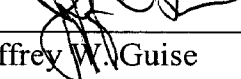
☐ The information disclosure statement submitted in the earlier application complied with paragraphs (a) through (c) of 37 CFR §1.98.

- I. ☒ *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$180.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.33547-731.302).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: 8-3-07

By: 
Jeffrey W. Guise
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Customer No. 021971

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/733,532
				Filing Date	December 11, 2003
				First Named Inventor	Julian Edward SALE
				Art Unit	1636
				Examiner Name	Daniel M. Sullivan
Sheet	1	Of	13	Attorney Docket Number	33547-731.302

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	US-5,750,335	05-12-1998	Gifford	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
	2.	WO-1995-12689 A1	05-11-1995	Gene Check Inc.		
	3.	WO-1993-12228 A1	06-24-1993	Pasteur Institut		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	4.	ADETUGBO, K. et al., "Molecular analysis of spontaneous somatic mutants," Nature 265:299-304 (1977)	
	5.	BAHLER, D.W. and LEVY, R., "Clonal evolution of a follicular lymphomas: Evidence for antigen selections," PNAS USA 89:6770-6774 (1992)	
	6.	BASS, S. et al., "Hormone Phage: An Enrichment Method for Variant Proteins With Altered Binding Properties," Proteins 8:309-314 (1990)	

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	7.	BEREK, C. and MILSTEIN, C., "The dynamic nature of the antibody repertoire," Immunol. Rev. 105:5-26 (1988)	
	8.	BETZ, A.G., et al., "Elements Regulating Somatic Hypermutation of an Immunoglobulin K Gene: Critical Role for the Intron Enhancer/Matrix Attachment Region," Cell 77:239-248 (1994)	
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	10.	BEZZUBOVA, O. et al., "Reduced X-ray resistance and homologous recombination frequencies in a RAD54-/-mutant of the chicken DT40 cell line," Cell 89:185-193 (1997)	
	11.	BONFIELD, J.K. et al., "A new DNA-sequence assembly program," Nucleic Acids Res. 23:4992-4999 (1995)	
	12.	BOUVET, J.P. and DIGHIRO, G., "From natural polyreactive autoantibodies to a la carte monoreactive antibodies to infectious agents: is it a small world after all?" Infect. Immun. 66:1-4 (1998)	
	13.	BRAEUNINGER, A. et al., "Hodgkin and Reed-Sternberg cells in lymphocyte predominant disease represent clonal populations of germinal center-derived tumor B cells," PNAS USA 94:9337-9342 (1997)	

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	14.	BRENNEMAN, M.A. et al., "XRCC3 is required for efficient repair of chromosome breaks by homologous recombination," Mutat. Res. 459:89-97 (2000)	
	15.	BROSS, L. et al., "DNA double-strand breaks in immunoglobulin genes undergoing somatic hypermutation," Immunity 13:589-597 (2000)	
	16.	BRUGGEMANN, M. et al., "Immunoglobulin V region variants in hybridoma cells. I. Isolation of a variant with altered idiotype and antigen binding specificity," EMBO J. 1:629-634 (1982)	
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	20.	CHAPMAN, C.J. et al. "Analysis of VH genes used by neoplastic B cells in endemic Burkitt's lymphoma shows somatic hypermutation and intracloal heterogeneity," Blood 85:2176-2181 (1995)	

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	21.	CHAPMAN, K.B. and SZOSTAK, J.W., "In vitro selection of catalytic RNAs," Curr. Op. Struct. Biol. 4:618-622 (1994)	
	22.	CHUI, Y.L. et al., "A reporter gene to analyse the hypermutation of immunoglobulin genes," J. Mol. Biol. 249:555-563 (1995)	
	23.	CLACKSON, T. and WELLS, J.A., "In vitro selection from protein and peptide libraries," Trends Biotechnol. 12:173-184 (1994)	
	24.	COFFINO, P. and SCHARFF, M.D., "Rate of somatic mutation in immunoglobulin production by mouse myeloma cells," PNAS USA 68:219-223 (1971)	
	25.	CUI, X. et al., "The XRCC2 and XRCC3 repair genes are required for chromosome stability in mammalian cells," Mutat. Res. 434:75-88 (1999)	
	26.	CULL, M.G. et al., "Screening for receptor ligands using large libraries of peptides linked to the C terminus of the lac repressor," PNAS USA 89:1865-1869 (1992)	
	27.	DEANS, B. et al., XRCC2 is required for genetic stability, embryonic neurogenesis and viability in mice," Embo J. 19:6675-6685 (2000)	
	28.	DENEPOUX, S. et al., "Induction of somatic mutation in a human B cell line in vitro," Immunity 6:35-46 (1997)	

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	29.	DIAZ, M. et al., "Evolution and the molecular basis of somatic hypermutation of antigen receptor genes," Philos. Trans. R. Soc. Lond. B Biol. Sci. 356:67-72 (2001)	
	30.	DRAKE, J.W., "Rates of spontaneous mutation," Genetics 148:1667-1686 (1998)	
	31.	ELLINGTON, A.D. and SZOSTAK, J.W., "In vitro selection of RNA molecules that bind specific ligands," Nature 346:81822 (1990)	
	32.	GOLD, L. et al., "Diversity of Oligonucleotide Functions," Annual Rev. Biochem. 65:763-797 (1995)	
	33.	GONZALEZ-FERNANDEZ and MILSTEIN, "Analysis of somatic hypermutation in mouse Peyer's patches using immunoglobulin κ light-chain transgenes," PNAS USA 90:9862-9866 (1993)	
	34.	GOOSSENS, T. et al., "Frequent occurrence of deletions and duplications during somatic hypermutation: Implications for oncogenic translocations and heavy chain disease," PNAS USA 95:2463-2468 (1998)	
	35.	GOYENECHEA, B. et al., "Cells strongly expressing Igk transgenes show clonal recruitment of hypermutation: a role for both MAR and the enhancers," Embo J. 16:3987-3994 (1997)	

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	37.	GREEN, N.S. et al., "IG V Region Hypermutation in B Cell Hybrids Mimics In Vivo Mutation and Allows for Isolation of Clonal Variants," Mol. Immunol. 34(15):1095-1103 (1997)	
	38.	GREEN, R. and SZOSTAK, J.W., "Selection of a Ribozyme That Functions as a Superior Template in a Self-Copying Reaction," Science 258:1910-1915 (1992)	
	39.	GRIFFIN, C.S. et al., "Mammalian recombination-repair genes XRCC2 and XRCC3 promote correct chromosome segregation," Nat. Cell Biol. 2:757-761 (2000)	
	40.	JAIN, R. et al., "A potential role for antigen selection in the clonal evolution of Burkitt's lymphoma," J. Immunol. 153:45-52 (1994)	
	41.	JOHNSON, R.D. et al., "Mammalian XRCC2 promotes the repair of DNA double-strand breaks by homologous recombination," Nature 401:397-399 (1999)	
	42.	JOLLY, C.J. et al., "Rapid methods for the analysis of immunoglobulin gene hypermutation: application to transgenic and gene targeted mice," Nucleic Acids Research 25(10):1913-1919 (1997)	

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				Filing Date	December 11, 2003
				First Named Inventor	Julian Edward SALE
				Art Unit	1636
				Examiner Name	Daniel M. Sullivan
Sheet	7	Of	13	Attorney Docket Number	33547-731.302

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